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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,100	11/21/2001	Takashi Fujita	01626C/HG	2878

1933 7590 05/21/2002

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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5

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-9 are pending in the application.
- ☐ Claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 1-9 is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☒ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 3
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

Claims 1-9 are pending in the application.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23, 25, 30 and 32-116 of U.S. Patent No. 5,886,014. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent differ only by generic description. See, especially, the compound of claim 25 in the patent which differs from the instant claims in that a specific pharmaceutically acceptable salt is not claimed. One skilled in the art would thus be motivated to prepare a pharmaceutically acceptable salt of a known compound (e.g. hydrochloride salt) to arrive at the instant claimed product with the expectation of increasing solubility and hygroscopicity of the known parent (or base) compound. Therefore, the

instant claimed invention would have been suggested to one skilled in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujita et al. {U.S. Pat. 5,886,014}.

Fujita et al. disclose the parent (or base) compound, that pharmaceutically acceptable salts are preferred, especially the hydrohalic acids, such as hydrochloric acid (compound I-49 in column 29; column 22, lines 23-25, 36 and 37; and column 160, lines 1-37). Therefore, Fujita et al. anticipate the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujita et al. {U.S. Pat. 5,886,014}, especially in view of the teaching in Berge et al. {Journal of Pharmaceutical Sciences (January 1977), Volume 66, No. 1, pages 1-19}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim the hydrochloride salt of a thiazolidin-2,4-dione compound. Fujita et al. teach a hydrochloride salt of a thiazolidin-2,4-dione compound (column 29, compound I-49; column 24, line 30; and column 22, lines 23-25, 36 and 37; and column 160, lines 1-37).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference, if any, is the selection of the particular pharmaceutically acceptable salt.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The selection of the hydrochloride salt of a known compound is *prima facie* obvious. Fujita et al. teach that pharmaceutically acceptable salts are preferred (column 22, lines 36-37). Fujita et al. also teach that the hydrohalic acids, such as hydrochloric acid, are preferred (column 22, lines 23-25). Berge et al. teach that the hydrochloride salt is a FDA approved salt and the mono-protic hydrochlorides have been the most frequent choice of the available anionic salt-forming radicals (page 2, columns 1 and 2). Berge et al. further teach that, "The salt form is known to influence a number of physicochemical properties of the parent compound including dissolution rate, solubility, stability and hygroscopicity" (page 5, column 1). One skilled in the art would thus be motivated to prepare the hydrochloride salt of a known compound to arrive at the instant claimed invention with the expectation of improving

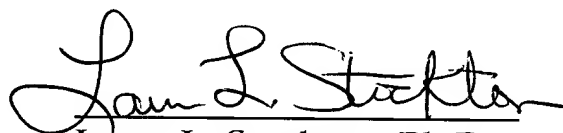
properties of the parent (or base) compound such as solubility and hygroscopicity. Therefore, the instant claimed invention would have been suggested to one skilled in the art.

The showing in the instant specification on pages 7 and 8 has been considered. Berge et al. on page 1, column 1, states, "The chemical, biological, physical and economic characteristics of medicinal agents can be manipulated and, hence, often optimized by conversion to a salt form." Berge et al. also teach that the hydrochloride salt is a FDA approved salt and the mono-protic hydrochlorides have been the most frequent choice of the available anionic salt-forming radicals (page 2, columns 1 and 2). Berge et al. further teach that, "The salt form is known to influence a number of physicochemical properties of the parent compound including dissolution rate, solubility, stability and hygroscopicity" (page 5, column 1). Therefore, the showing is not persuasive because the result is not unexpected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235, 308-0196 or 305-3290.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556, 308-4242, 305-1935 or 308-2742.

A handwritten signature in black ink, appearing to read 'Laura L. Stockton', written over a horizontal line.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

May 20, 2002